PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :		(11) International Publication Number:
A61N 1/372, 1/05, A61F 11/04 A61F 2/18	A1	WO 89/ 00870
		(43) International Publication Date: 9 February 1989 (09.02.89)

(21) International Application Number: PCT/AU88/00265

(22) International Filing Date: 22 July 1988 (22.07.88)

(31) Priority Application Number: 077,445

(32) Priority Date: 24 July 1987 (24.07.87)

(33) Priority Country: US

(71) Applicant: COCHLEAR PTY. LTD. [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU).

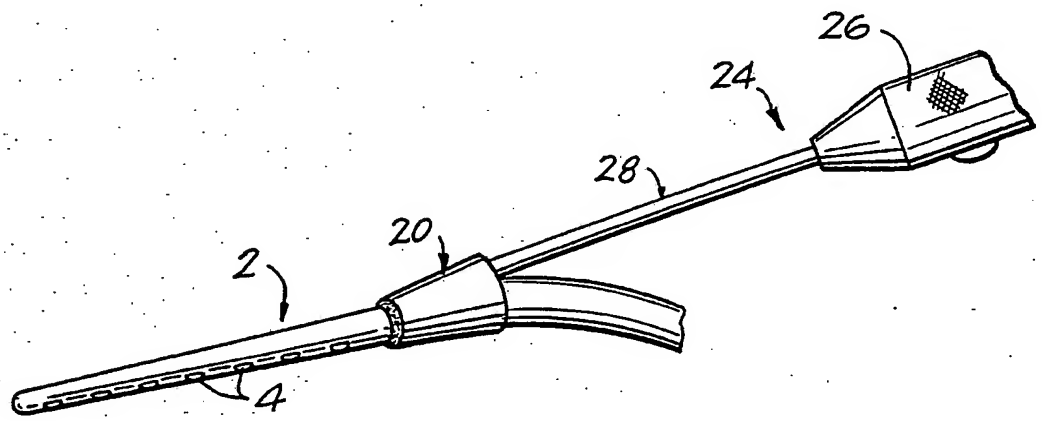
(72) Inventor: KUZMA, Janusz ; 27 Solander Road, Kings Langley, NSW 2147 (US).

(74) Agent: SHELSTON WATERS; 55 Clarence Street, Sydney, NSW 2000 (AU).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: APPARATUS AND METHOD FOR INSERTION OF COCHLEAR ELECTRODE ASSEMBLY



(57) Abstract

An apparatus and method for insertion of a cochlear implant. The method includes sliding a collar (20) on to the rear end of a cochlear electrode (4) lead (2), applying glue to the forward end of the collar, and putting a gripping tool (24) configured for squeeze-fit placement in the free rear end of the collar (20).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg	TG	Togo
DK	Denmark	MC	Monaco	US	United States of America
FI	Finland	MG	Madagascar		

Description

APPARATUS AND METHOD FOR INSERTION OF COCHLEAR ELECTRODE ASSEMBLY

This invention relates to an insertion tool for a cochlear implant, and a method for using that tool to insert a cochlear electrode lead into a patient's ear.

The stimulating electrode assembly of a cochlear implant is placed inside the cochlear partition, commonly into the scala tympani. A major problem with conventional electrode leads is in inserting them into the cochlea without irreversibly damaging the auditory nerve fibers, and the electrodes and lead wires of the electrode lead. In the prior art, electrode leads are surgically inserted along the line of sight through the round window and along the basal turn of the cochlea, either with an alligator forceps or with Y-shaped claws. The alligator forceps adequately control the force and direction of the electrode insertion, but risk of damage to the electrodes is high. The forceps also must be periodically removed and replaced to correctly orient the electrode array in the cochlea, since it can grip the electrode lead only through a limited angle of rotation.

The Y-shaped claws minimize damage to the electrode, but it cannot be used to apply insertion force in the optimum direction, along the line of sight. Since it cannot grip the electrode lead, it also cannot be used to rotate the electrode to correctly place it in the cochlea.

An object of my invention is to provide an insertion tool and a technique for insertion of the electrode lead which both protects the electrode assembly and allows successful manipulation of the electrode lead into the cochlea.

In accordance with the principals of my invention, the electrode lead is provided with a collar, preferably made of silicone rubber. The collar is affixed to the rear of the electrode lead at a predetermined point above the electrode assembly. The collar is expanded in Freon or

other suitable gas, so that the inner diameter of the collar is slightly greater than the outer diameter of the electrode lead. This enables the collar to slip over the lead during manufacture. After placement of the collar, the Freon evaporates, and the collar returns to its original dimensions (equivalent to the outer diameter of the lead). This shrinking results in a snug friction fit. Glue (preferable silastic A) is applied to the forward edges of the collar. The collar is positioned so that it is located outside the round window after insertion is completed.

The insertion or gripping tool has a rounded end, configured like a thumbnail at the tip, designed to fit between the collar and the lead. A major advantage of my invention is that the squeeze or friction fit of the gripping tool to the electrode lead (through the collar) completely prohibits possible damage to the electrode array as may occur with use of alligator forceps. This mode of attachment also permits optimum application of the insertion force directly along the axis. Further, the surgeon can use the gripping tool to rotate the electrode lead without fear that the tool will slip off the lead and damage the electrode assembly or the delicate tissues of the patient's ear. This contrasts with the prior art Y-shaped claws which cannot be used to apply force along the line of sight or to grip and rotate the electrode lead. Although the prior art alligator forceps adequately control the force and direction of the electrode insertion, it must be periodically removed from the lead and replaced at a point further back on the lead in order to completely insert the electrode lead into the cochlea. With my invention, the surgeon may apply constant forward force along the axis without removing the gripping tool at all.

My invention can also be used with both symmetric and non-symmetric electrodes. With non-symmetric electrodes, the gripping tool is placed under the collar so that

it is directly above the active electrodes (e.g. 180 degrees away). A mark is placed on the front of the handle of the gripping tool so that when the surgeon inserts the electrode lead into the cochlea and the electrode assembly is no longer visible, the surgeon is able to determine he orientation of the active electrodes and to rotate the electrode lead to correctly place the active electrode assembly in the cochlea. With symmetric electrodes, the placement of the tool with respect to the array is not important.

After insertion of the electrode array is completed, the gripping tool is removed by sliding it along the axis of the lead; the lead can be held steady (so that removal of the tool does not remove the lead) by temporary placement of the Y-shaped claws on the collar.

Further objects, features, and advantages of my invention will become apparent upon consideration of the following detailed description in conjunction with the drawings, in which:

FIG. 1A is an illustration of a prior art non-symmetric electrode lead;

FIG. 1B is an illustration of a prior art symmetric electrode lead;

FIG. 2 illustrates the prior art method of inserting the electrode lead into the cochlea;

FIGS. 3A-C illustrate the preferred method of placing the collar around the electrode lead during manufacture;

FIG. 4A is an illustration of the gripping tool;

FIG. 4B is an enlarged view of the tip of the gripping tool;

FIG. 5A-C illustrate the preferred method of using the insertion tool with the electrode lead.

Fig. 1A is an illustration of a prior art non-symmetric or localized electrode lead 2, with active electrodes 4 and electrode lead wires 6. Fig. 1B shows a prior art symmetric or banded electrode lead 8, with active electrodes 10 and electrode lead wires 12. The prior art method of inserting an electrode lead into the cochlea is shown in Fig. 2. To achieve insertion, force must be

applied along the axis of electrode lead 8 (direction I). When prior art Y-shaped claws 14 are used, this force is generated from friction between the claws and the lead. Since the lead is smooth and slippery, a large force F, normal to the axis, is required, which may result in bending or undesirable rotation of the lead. Further, in order to push lead 8 through round window 16 and along basal turn 18 of the cochlea, the surgeon must periodically remove and replace claws 14 (from position A to B in Figure 2).

In the preferred embodiment of my invention, a collar is placed on the electrode lead to the rear of the electrode assembly. In Figs. 3A-3C, the preferred method of placing collar 20 around electrode lead 8 is illustrated. In Fig. 3A, a 5-6mm length collar 20, made of silastic tubing, silicone rubber or other suitable material, is slipped over the front end of lead 8 to rest at a point approximately 26mm behind the last electrode. Collar 20 is expanded in Freon to produce an inner diameter of 0.6 mm, which is slightly larger than the outer diameter of electrode lead 8, so as to facilitate placement of collar 20 over lead 8 and to allow for a snug friction fit after evaporation of the Freon. Collar 20 has a wall thickness of 0.2-0.3 mm. Fig. 3B shows the placement of collar 20 on lead 8. In Fig. 3C, an enlarged view of collar 20 and lead B, glue 22 (preferably silastic A) is applied to the front edges of collar 20, permanently affixing collar 20 to lead 8.

Figs. 4A and 4B show gripping tool 24 which is adapted for use with collar 20. Fig. 4A is an illustration of gripping tool 24, with a 110 mm length handle 26 and a 40 mm tip 28. Fig. 4B is an enlarged view of the front of tip 28, with all sharp edges removed to form a rounded end 30, with a length of 3-3.5 mm. In Fig. 5A, rounded end 30 is placed gently under the rear end of collar 20, allowing the tip of the insertion tool to be attached to lead 8, removed

from the vicinity of the electrodes themselves. Fig. 5B is an enlarged view of the location of rounded groove 30 under collar 20.

This technique of attachment permits the surgeon to apply force directly along the axis, in the optimum direction along the line of sight through the round window. Possible damage to the electrode lead is minimized, and the surgeon does not need to periodically remove and replace the gripping tool to push the lead forward. The friction fit of the gripping tool to the lead also permits the surgeon to rotate the lead and correctly orient it in the cochlea without fear that the tool may slip off the lead. When the tool is used to insert non-symmetric or localized electrode lead 2 in Fig. 5C, the gripping tool is placed 180 degrees from active electrodes 4, and a mark is placed on the front of handle 26, indicated the direction of the active electrodes. This enables the surgeon to determine the location of active electrodes 4 when the lead has been inserted through the round window and the active electrodes are no longer visible, permitting the surgeon to correctly orient the active electrodes with respect to the cochlear nerves.

After insertion of the electrode assembly is completed, the collar is located outside the round window. Removal of the gripping tool from the collar is accomplished by sliding the tool along the axis of the lead; the lead can be held steady (so that removal of the tool does not remove the electrode assembly from the cochlea) by the temporary placement of prior art Y-shaped claws on the collar.

Although the invention has been described with reference to a particular embodiment it is to be understood that this embodiment is merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

CLAIMS

1. A cochlear electrode lead comprising an assembly of electrodes at one end and a collar attached to the rear of said assembly which facilitates placement of a gripping tool.

2. A cochlear electrode lead in accordance with claim 1 wherein said collar is configured to prevent slippage between the gripping tool and the lead as the gripping tool is turned to rotate the lead.

3. A cochlear electrode lead in accordance with claim 1, wherein said collar is a length or tubing affixed to the lead at only its forward end.

4. A cochlear electrode lead in accordance with claim 3 wherein said gripping tool is configured at one end for squeeze-fit placement in the free rear end of the collar.

5. A method of making an insertion mechanism for the lead of a cochlear implant, comprising the steps of:

(a) sliding a collar onto the rear end of the lead, and

(b) applying glue to the forward end of the collar.

6. A cooperating cochlear implant lead and gripping tool, comprising a cochlear implant lead having a collar whose forward end is fixed to the rear of the lead; and a tool having a handle at one end, with the other end being configured for squeeze-fit placement in the free rear end of said collar.

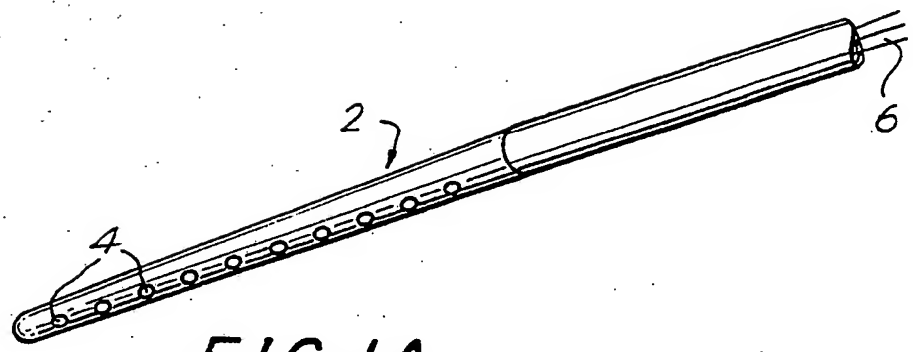


FIG. 1A
PRIOR ART

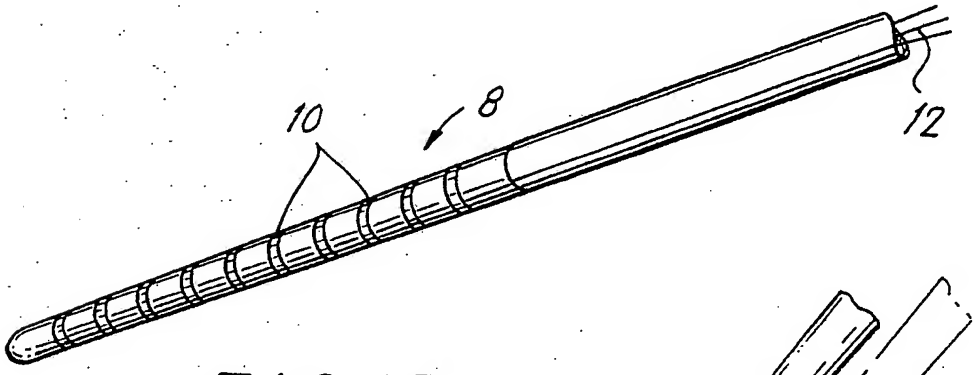


FIG. 1B
PRIOR ART

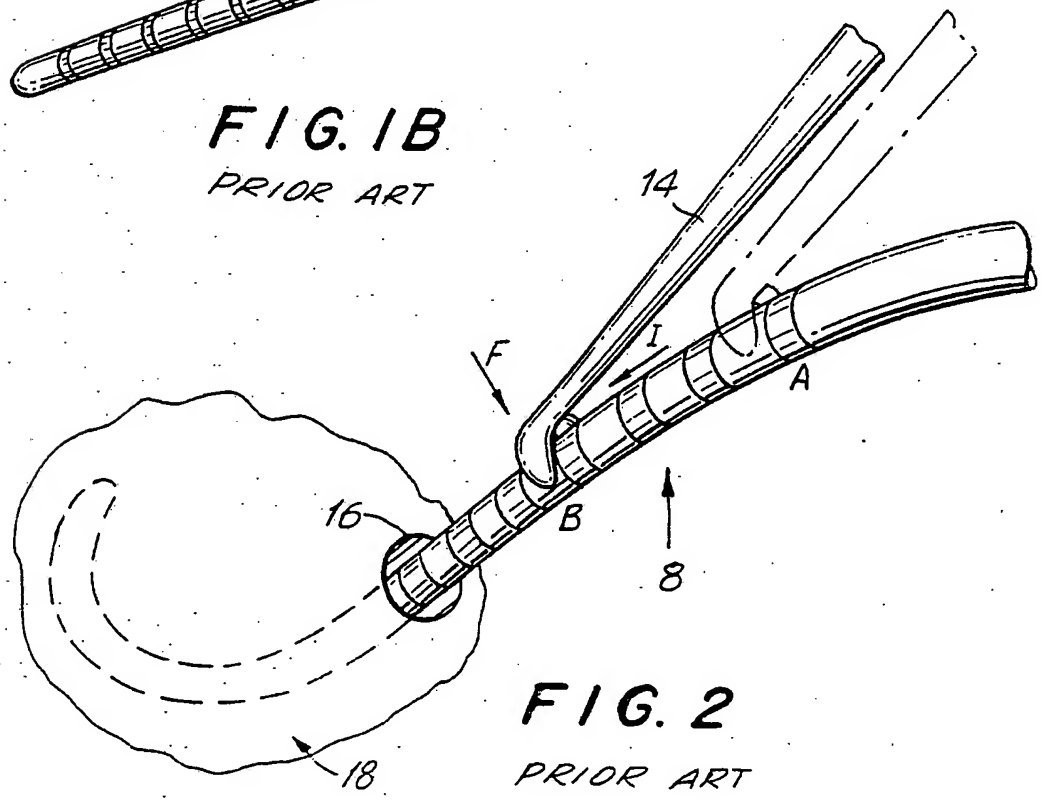
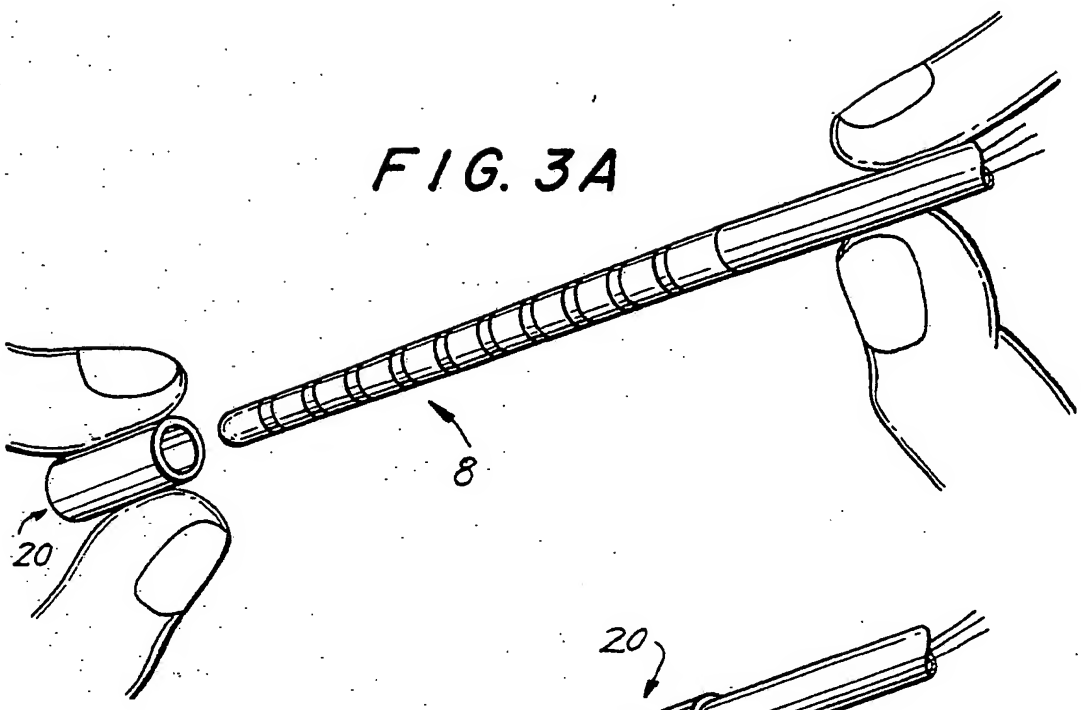


FIG. 2
PRIOR ART

FIG. 3A



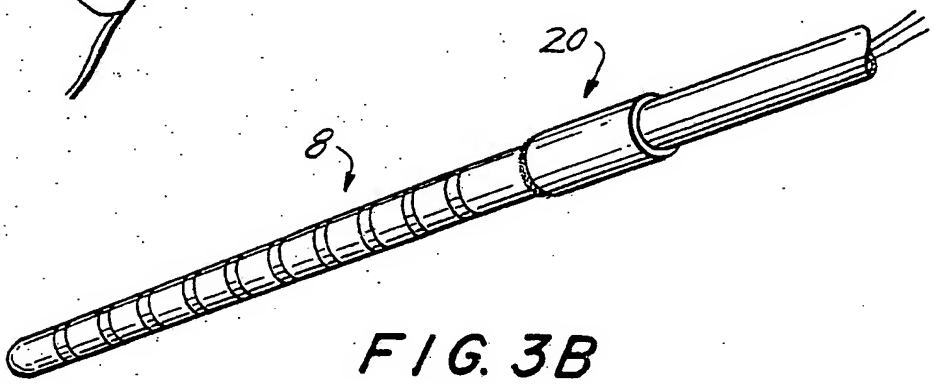


FIG. 3B

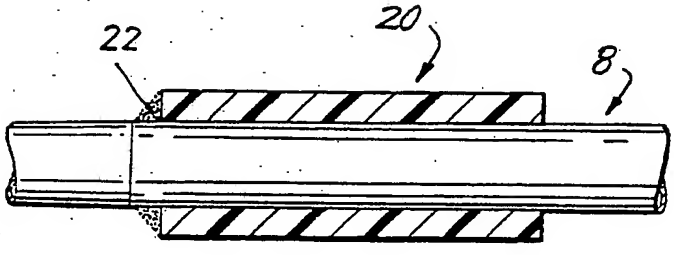


FIG. 3C

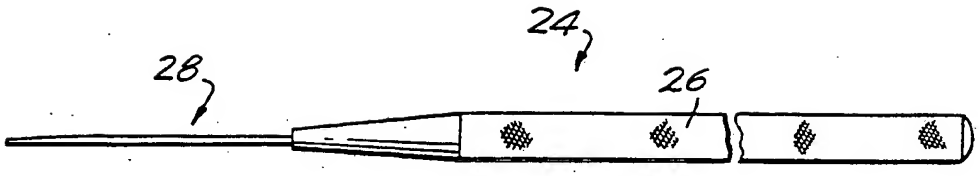


FIG. 4A

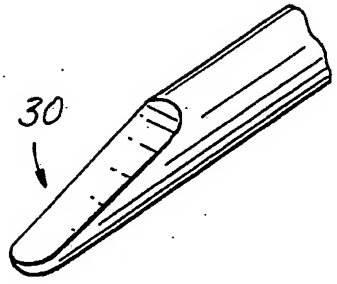


FIG. 4B

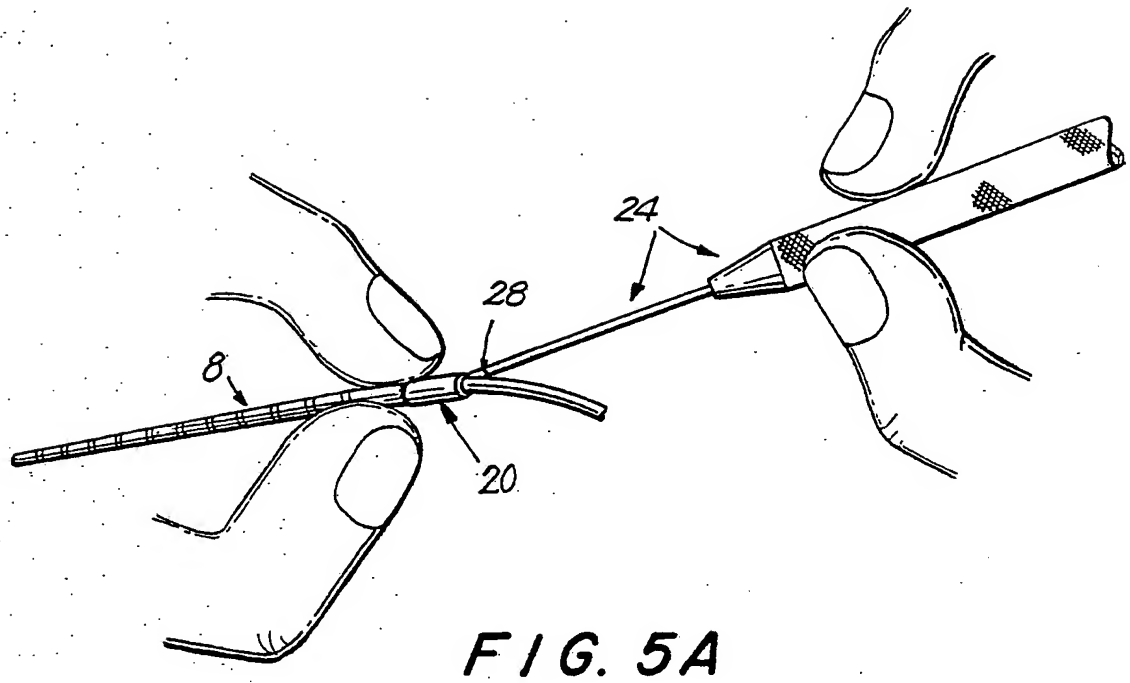


FIG. 5A

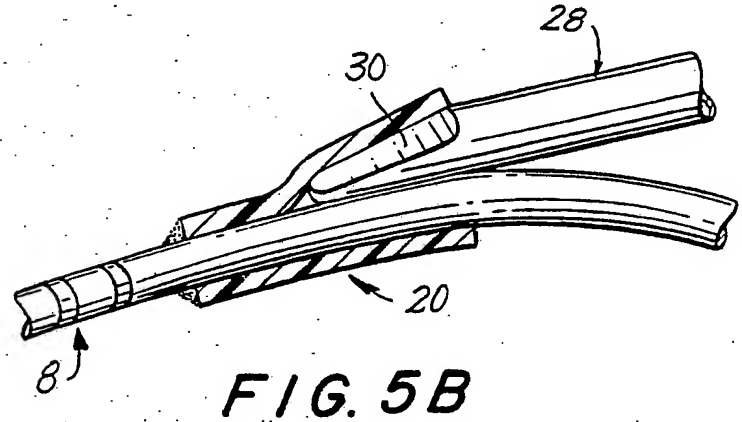


FIG. 5B

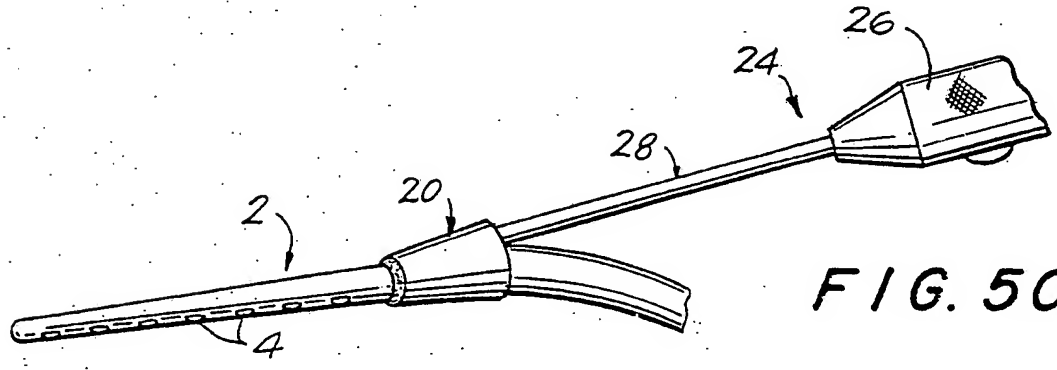


FIG. 5C

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 88/00265

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61N 1/372, 1/05; A61F 11/04, 2/18

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
IPC	A61N 1/02, 1/04, 1/05, 1/36, 1/372

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

AU : IPC as above; A61F 2/18, 11/04; H04R 25/00

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	WO,A, 80/02231 (DONACHY, J.H. et al) 30 October 1980 (30.10.80)	
A	EP,A, 109-304 (MINNESOTA MINING MFG. CO.) 23 May 1984 (23.05.84)	
A	AU,A, 41600/78 (HANSEN, C.C. et al) 28 June 1979 (28.06.79)	
A	AU,B, 46563/79 (529974) (THE UNIVERSITY OF MELBOURNE) 29 November 1979 (29.11.79)	
A	EP,A, 85-417 (MEDTRONIC INC.) 10 August 1983 (10.08.83)	
A	US,A, 4514589 (ALDINGER, F. et al) 30 April 1985 (30.04.85)	
A	GB,A, 2057272 (CARDIAC RECORDERS LTD.) 1 April 1981 (01.04.81)	

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
28 September 1988 (28.09.88)	21 OCTOBER 1988 (21.10.88)
International Searching Authority: Australian Patent Office	Signature of Authorized Officer: R.A. MURRAY

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 88/00265

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members		
US 4514589	DE 3134896	EP 73881	
EP 85417	JP 58133262	US 4414986	
GB 2057272			
EP 109304	JP 59101148 US 4462402	US 4487210 AU 21310/83	US 4462401
AU 41600/78	DK 5166/77		
AU 46563/79	CA 1115352 EP 176233	EP 7157	JP 55000190
WO 8002231	AU 59979/80	EP 27465	

END OF ANNEX